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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

Richard Skinner,

No. CV-23-01051-PHX-MTL

Plaintiff,

ORDER

V.

**Small Bone Innovations Incorporated, et al.,
Defendants.**

Pending before the Court is Defendant Small Bones Innovations Incorporated’s (“SBI”) Motion to Dismiss Plaintiff Richard Skinner’s Complaint. (Doc. 10.) The Motion is fully briefed.¹ (Doc. 10; Doc. 15; Doc. 16.) For the following reasons, the Court will grant the Motion.

I. BACKGROUND

The following facts are taken from the allegations in the Complaint, which the Court accepts as true and construes in the light most favorable to Plaintiff. *North Star Int'l. v. Arizona Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983).

In October of 2013, Plaintiff required surgery for his ankle and received a Scandinavian Total Ankle Replacement (“STAR”), the medical device at issue in this action. (Doc. 1 ¶ 6.) Subsequently, Plaintiff experienced symptoms of pain and instability in his affected ankle. (*Id.* ¶ 7.) Defendant SBI is a Pennsylvania corporation that

¹ The request for oral argument is denied, as both parties have fully briefed the issues and oral argument would not have significantly aided the Court's decisional process. See *Partridge v. Reich*, 141 F.3d 920, 926 (9th Cir. 1998); see also LRCiv 7.2(f); Fed. R. Civ. P. 78(b).

1 “designed, manufactured, tested inspected, warranted and marketed the STAR ankle
 2 replacement.” (*Id.* ¶¶ 2, 12.) On October 11, 2019, an unidentified entity issued a safety
 3 communication, advising the public that parts of the STAR device “were fracturing with
 4 loss of mechanical properties” and “occurring substantially more often than with
 5 comparable total ankle replacements.” (*Id.* ¶ 8.) The Federal Drug Administration also
 6 issued a safety alert to the same effect. (*Id.* ¶ 9.) Plaintiff asserts that he became aware of
 7 the STAR’s defects on June 13, 2022, after he received a CAT scan and was informed
 8 that the STAR product degraded and was shedding plastic into his body. (*Id.* ¶ 10.) On
 9 June 7, 2023, Plaintiff filed a Complaint with this Court, alleging strict product liability
 10 and negligence claims against Defendant SBI for its defective STAR device. (*Id.*
 11 ¶¶ 11-26.) In response, Defendant filed the pending Motion to Dismiss, arguing that
 12 Plaintiff’s Complaint fails to state a claim for relief. (Doc. 10.)

13 **II. STANDARD OF REVIEW**

14 Dismissal for failure to state a claim under Federal Rule of Civil Procedure
 15 12(b)(6) may be based on either a “lack of a cognizable legal theory” or ‘the absence of
 16 sufficient facts alleged under a cognizable legal theory.’” *Johnson v. Riverside*
 17 *Healthcare Sys., LP*, 534 F.3d 1116, 1121–22 (9th Cir. 2008) (quoting *Balistreri v.*
 18 *Pacifica Police Dep’t*, 901 F.2d 696, 699 (9th Cir. 1990)). In determining whether a
 19 complaint states a claim under this standard, the allegations in the complaint are taken as
 20 true and the pleadings are construed in the light most favorable to the nonmovant.
 21 *Knievel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005). A pleading must contain “a short
 22 and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R.
 23 Civ. P. 8(a)(2). But “[s]pecific facts are not necessary; the statement need only give the
 24 defendant fair notice of what . . . the claim is and the grounds upon which it rests.”
 25 *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (internal quotation omitted). To survive a
 26 motion to dismiss, a complaint must state a claim that is “plausible on its face.” *Ashcroft*
 27 *v. Iqbal*, 556 U.S. 662, 678 (2009); see *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544,
 28 570 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that

1 allows the court to draw the reasonable inference that the defendant is liable for the
 2 misconduct alleged.” *Iqbal*, 556 U.S. at 678.

3 Generally, when deciding a Rule 12(b)(6) motion, the court looks only to the face
 4 of the complaint and documents attached thereto. *Van Buskirk v. Cable News Network,*
 5 *Inc.*, 284 F.3d 977, 980 (9th Cir. 2002); *Hal Roach Studios, Inc. v. Richard Feiner & Co.,*
 6 *Inc.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1990). If a court considers evidence outside the
 7 pleading, it must convert the Rule 12(b)(6) motion into a Rule 56 motion for summary
 8 judgment. *United States v. Ritchie*, 342 F.3d 903, 907–08 (9th Cir. 2003). A court may,
 9 however, consider documents incorporated by reference in the complaint or matters of
 10 judicial notice without converting the motion to dismiss into a motion for summary
 11 judgment. *Id.*

12 **III. DISCUSSION**

13 **A. Judicial Notice**

14 In addition to its Motion, Defendant asks the Court to take judicial notice of
 15 various documents, including Defendant’s initial Premarket Approval (“PMA”) records
 16 from the Food and Drug Administration’s (“FDA”) website (Doc. 10, Ex. 1), a May 27,
 17 2009 PMA letter from the FDA (Doc. 10, Ex. 2), and three PMA supplemental
 18 applications (Doc. 10, Ex. 3–5.) All these documents are publicly available. (Doc. 10 at
 19 5–7.) These additional facts establish that Defendant SBI’s STAR device is a Class III
 20 medical device that underwent the FDA’s comprehensive PMA process in December
 21 2005, and was approved by the FDA on May 27, 2009. (*Id.*; Doc. 10, Ex. 1–2.) Plaintiff
 22 has not objected to Defendant’s request for judicial notice. (See Doc. 15.)

23 Generally, when assessing the sufficiency of a complaint under Rule 12(b)(6),
 24 courts may not consider material outside the pleadings. *Lee v. City of Los Angeles*, 250
 25 F.3d 668, 688 (9th Cir. 2001); *see also* Fed. R. Civ. P. 12(d) (explaining that if a court
 26 considers matters outside the pleadings, the Rule 12 motion “must be treated as one for
 27 summary judgment under Rule 56”). There are, however, two exceptions to this rule: (1)
 28 the incorporation-by-reference doctrine, and (2) judicial notice under Federal Rule of

1 Evidence 201. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018).
 2 Rule 201 of the Federal Rules of Evidence permits a court to notice an adjudicative fact if
 3 it is “not subject to reasonable dispute.” *Id.* (citing Fed. R. Evid. 201(b)). A fact is “not
 4 subject to reasonable dispute” if it is “generally known,” or “can be accurately and
 5 readily determined from sources whose accuracy cannot reasonably be questioned.” *Id.*

6 Because these exhibits are matters of public record and not subject to reasonable
 7 dispute, the Court grants Defendant’s request for judicial notice. *See Stengel v.*
 8 *Medtronic, Inc.*, 676 F.3d 1159, 1167 (9th Cir. 2012), *rev’d en banc on other grounds*,
 9 704 F.3d 1224 (9th Cir. 2013) (affirming district court’s judicial notice of FDA’s grant of
 10 PMA); *Arvizu v. Medtronic Inc.*, 41 F. Supp. 3d 783, 785 n.3 (D. Ariz. 2014) (granting
 11 request for judicial notice of documents related to the PMA process).

12 **B. The Medical Device Amendments and Federal Preemption**

13 Prior to the passage of the Medical Device Amendments (“MDA”), “the
 14 introduction of new medical devices was left largely for the States to supervise as they
 15 saw fit.” *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–16 (2008). But in 1976, Congress
 16 enacted the MDA to the Federal Food, Drug and Cosmetic Act (“FDCA”), imposing an
 17 exclusive, federal regime of oversight for medical devices. *See* 21 U.S.C. § 360c *et seq.*;
 18 *Riegel*, 552 U.S. at 316–17. The MDA established a hierarchy of three categories of
 19 medical devices, each with different levels of regulatory scrutiny according to their risk.
 20 21 U.S.C. § 360c.

21 Medical devices in Class I pose the lowest risk to health and safety, and thus, are
 22 subject to “general controls” such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A);
 23 *Riegel*, 552 U.S. at 316. Class II devices pose a higher risk and are subject to “general”
 24 and “specific controls,” such as performance standards and postmarket surveillance
 25 measures. 21 U.S.C. § 360c(a)(1)(A). Class III devices pose the greatest risk, and
 26 therefore, receive the most extensive federal oversight. *Id.* § 360c(a)(1)(C). Class III
 27 devices are “subject . . . to premarket approval” which is a process designed “to provide
 28 reasonable assurance of [the device’s] safety and effectiveness.” *Id.*; *see also* 21 U.S.C.

1 § 360e (describing the procedure for obtaining premarket approval). The application for
 2 premarket approval must include, among other things, “reports of all information,
 3 published or known to or which should reasonably be known to the applicant, concerning
 4 investigations which have been made to show whether or not such device is safe and
 5 effective” and “a full description of the methods used in, and the facilities and controls
 6 used for, the manufacture, processing, and, when relevant, packing and installation of
 7 such device.” *Id.* § 360e(c)(1)(A), (c)(1)(C). If a Class III device receives PMA—such as
 8 the STAR medical device in this action—the manufacturer cannot make any changes to
 9 the medical device affecting safety or effectiveness without a supplemental application
 10 for approval.² *Id.* § 360e(d)(5)(A)(i). The manufacturer must also report any information
 11 learned after receiving PMA that the device “may have caused or contributed to a death
 12 or serious injury,” or that the device malfunctioned and a similar device would likely
 13 cause or contribute to a death or serious injury. *Id.* § 360i(a)(1); *see also* 21 C.F.R. §
 14 803.50(a).

15 Congress enacted the MDA to sweep “back some state obligations and impose[] a
 16 regime of detailed federal oversight.” *Riegel*, 552 U.S. at 316. To achieve this, the MDA
 17 includes an express preemption provision, stating:

18 Except as provided in subsection (b) of this section, no State
 19 or political subdivision of a State may establish or continue in
 20 effect with respect to a device intended for human use any
 requirement—

- 21 (1) which is different from, or in addition to, any requirement
 applicable under this chapter to the device, and
- 22 (2) which relates to the safety or effectiveness of the device or
 to any other matter included in a requirement applicable to
 the device under this chapter.

24 21 U.S.C. § 360k(a); *see also* 21 C.F.R. § 808.1(d). Courts applying Section 360k use a
 25 two-prong test to determine whether a state law claim is expressly preempted. *Riegel*, 552

27 ² There are exceptions to this rule. A manufacturer may modify a device if the change is
 28 consistent with a predetermined change control plan approved under 21 U.S.C. § 360e-4,
 or if the change is a modification of manufacturing procedure and the holder of the PMA
 submits written notice to the Secretary. 21 U.S.C. § 360e(d)(5)(A)(i).

1 U.S. at 321–23. Under the first prong, a court considers whether the FDA has established
 2 requirements applicable to the device at issue. *Id.* If so, then the court considers whether
 3 the claims in the case attempt to impose state requirements relating to safety and
 4 effectiveness that are different from, or in addition to, the federal requirements. *Id.* If the
 5 answer to both questions is yes, then the claims are preempted by Section 360k. *Id.* The
 6 Ninth Circuit has explained that “for a state law claim regarding a Class III medical
 7 device to survive express preemption by the MDA, a plaintiff must establish that the
 8 defendant violated an FDA requirement.” *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1111
 9 (9th Cir. 2019).

10 A state law claim that avoids express preemption by Section 360k may still be
 11 impliedly preempted if the claim is not based on “traditional state tort law” and instead
 12 only attempts to enforce federal law. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S.
 13 341, 353 (2001). Claims premised solely on violations of federal regulations are
 14 preempted because “the federal statutory scheme amply empowers the FDA to punish
 15 and deter fraud against the Administration.” *Id.* at 348. Therefore, private litigants may
 16 not file suit against a manufacturer merely for its noncompliance with the FDA’s medical
 17 device provisions. *Id.* at 349 n. 4; *see also* 21 U.S.C. § 337(a) (“[A]ll such proceedings
 18 for the enforcement, or to restrain violations, of this chapter shall be by and in the name
 19 of the United States.”)

20 Consequently, a state law claim must fit the “narrow gap” between express and
 21 implied preemption. *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013). To
 22 avoid preemption, “[t]he plaintiff must be suing for conduct that violates the FDCA (or
 23 else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing
 24 because the conduct violates the FDCA (such a claim would be impliedly preempted
 25 under *Buckman*).” *Id.* State law claims that parallel a federal law duty under the MDA or
 26 FDCA fit this narrow gap and are not preempted. *Stengel v. Medtronic Inc.*, 704 F.3d
 27 1224, 1233 (9th Cir. 2013); *see also Lawrence v. Medtronic*, 791 F. App’x 679, 680 (9th
 28 Cir. 2020) (“To avoid preemption, a plaintiff bringing a state tort claim must allege that

1 the state-law duty at issue parallels a federal requirement.”).

2 **C. SBI’s Motion to Dismiss**

3 In its Motion, Defendant contends that dismissal is warranted because Plaintiff’s
 4 claims are: (1) expressly preempted by 21 U.S.C. § 360k; and (2) otherwise fail to state a
 5 claim for relief. (Doc. 10 at 7–11.) In his Response, Plaintiff argues that Defendant’s
 6 Motion is premature because he should have the opportunity to investigate whether
 7 Defendant complied with federal laws,³ that Plaintiff has alleged viable tort claims, and
 8 that Plaintiff’s claims are not preempted. (Doc. 15 at 1–2.) Specifically, as to preemption,
 9 Plaintiff argues that the presumption against preemption applies, that Plaintiff’s claims
 10 for failures in “testing, inspecting, warranty, marketing, lack of warnings, and packaging,
 11 each provide a basis of Arizona tort relief that is not expressly preempted,” and that
 12 Plaintiff has alleged parallel claims to avoid preemption. (*Id.* at 8–10.)

13 **i. The Presumption Against Preemption**

14 Before addressing Plaintiff’s strict liability and negligence claims, the Court first
 15 addresses his fleeting presumption against preemption argument. (*Id.* at 8.) The United
 16 States Supreme Court has recognized that where there is “an express pre-emption
 17 clause”—such as Section 360k here—courts do not invoke any presumption against
 18 preemption and instead “focus on the plain wording of the clause, which necessarily
 19 contains the best evidence of Congress’ pre-emptive intent.” *Puerto Rico v. Franklin*
 20 *California Tax-Free Tr.*, 579 U.S. 115, 125 (2016) (internal citation omitted); *see also*
 21 *Buckman*, 531 U.S. at 347–48 (holding that “no presumption against pre-emption obtains
 22 in this case” where the claims were based on fraudulent statements to the FDA).
 23 Therefore, and pursuant to *Puerto Rico*, the presumption against preemption does not
 24 apply here. *See also Jacob v. Mentor Worldwide, LLC*, 393 F. Supp. 3d 912, 923 (C.D.
 25 Cal. 2019), *aff’d sub nom. Nunn v. Mentor Worldwide, LLC*, 847 F. App’x 373 (9th Cir.
 26 2021) (applying *Puerto Rico* and holding that the presumption against preemption does

27 ³ Plaintiff is subject to the pleading requirements of Federal Rules of Civil Procedure 8(a)
 28 and 12(b)(6). The Court finds that Defendant’s Motion, challenging the legal sufficiency
 of the Complaint under Rule 12(b)(6), is not premature.

1 not apply where the MDA expressly preempts state tort law).

2 **ii. Count I: Strict Liability**

3 Plaintiff first asserts a claim of strict product liability against Defendant under
 4 Ariz. Rev. Stat § 12-681 *et seq.* (Doc. 1 ¶¶ 11–17.) Plaintiff avers that the “STAR ankle
 5 replacement was defective, unreasonably dangerous and unfit for its intended use and
 6 purposes because of its design, manufacture, testing, inspection, warranty, marketing,
 7 lack of warnings and packaging” at the time of Plaintiff’s surgery. (Doc. 1 ¶ 15.)
 8 Specifically, Plaintiff asserts that the STAR device was “subject to material degradation
 9 of the polyethylene component . . . causing the plastic within the device [] to fracture.”
 10 (*Id.* ¶ 15.) Plaintiff alleges that because Defendant manufactured and designed the STAR
 11 device, and Plaintiff’s injuries were a direct and proximate result of the device’s defects,
 12 it is strictly liable for Plaintiff’s injuries. (*Id.* ¶¶ 11–17.)

13 In the pending Motion, Defendant argues that Plaintiff’s strict liability claim is
 14 legally insufficient because Plaintiff has not adequately pleaded a design defect,
 15 manufacturing defect, or negligent manufacturing claim under Arizona law. (Doc. 10 at
 16 7–8.) Defendant also contends that Plaintiff’s strict liability claims seek to impose
 17 additional design, manufacturing, or labeling requirements that are “different from or
 18 additional to” the FDA’s requirements. (*Id.* at 9–10 (quoting 21 U.S.C. § 360k(a)(1))).
 19 Because Plaintiff has not alleged any parallel claims to survive preemption, Defendant
 20 argues that Plaintiff’s strict liability claim is expressly preempted by Section 360k. (*Id.*)
 21 Plaintiff argues that the Complaint adequately alleges a strict liability claim under
 22 Arizona law and is not preempted. (Doc. 15 at 5–6, 8–10.)

23 To the extent Plaintiff alleges a design defect claim, that claim is expressly
 24 preempted by Section 360k. *See Arvizu*, 41 F. Supp. 3d at 792. In *Arvizu*, the plaintiffs
 25 brought strict liability claims against defendant manufacturers, alleging that an “Infuse
 26 Device,” a Class III device that received premarket approval from the FDA, was
 27 defectively designed. *Id.* at 785. The court explained that to prevail on this claim, the
 28 plaintiffs would need to show that the Infuse Device should have been designed in a

1 manner different from what the FDA approved, and this “would impose requirements that
 2 are different from or in addition to federal law.” *Id.* at 792. Because this showing would
 3 violate Section 360k, the court determined that the design defect claim was expressly
 4 preempted. *Id.* Similarly here, a design defect claim would require finding that the STAR
 5 device should have been designed differently than what was approved by the FDA.
 6 Because this would impose requirements that are “different from” or “in addition to” the
 7 MDA, Plaintiff’s strict liability claim based on a design defect is expressly preempted.
 8 *See* 21 U.S.C. § 360k(a).

9 Other courts have held that a design defect claim is not expressly preempted if a
 10 plaintiff alleges that the design approved by the FDA in the PMA process was not the
 11 same design used in production. *See In re Medtronic, Inc., Sprint Fidelis Leads Products*
 12 *Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (explaining that design-defect claims
 13 against a medical device approved by the FDA through the PMA process must “alleg[e]
 14 that the product sold . . . was not the product design approved in the PMA Supplement”);
 15 *Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (“To
 16 properly plead parallel claims that survive preemption, a plaintiff must allege facts (1)
 17 showing an alleged violation of FDA regulations or requirements related to [the device],
 18 and (2) establishing a causal nexus between the alleged injury and the violation.”)
 19 (internal quotation marks and citation omitted). But the present Complaint is devoid of
 20 comparable allegations sufficient to escape preemption. (*See* Doc. 1.)

21 To the extent Plaintiff alleges a manufacturing defect claim, that claim is also
 22 expressly preempted by Section 360k for the same reasons the design defect claim fails.
 23 *See Riegel*, 552 U.S. at 325; *Scovil v. Medtronic, Inc.*, 995 F. Supp. 2d 1082, 1095 (D.
 24 Ariz. 2014) (dismissing the plaintiffs’ manufacturing and design defect claims as
 25 preempted by Section 360k). A plaintiff, however, may avoid preemption if he or she
 26 alleges that the defendant “deviated from a particular pre-market approval or other FDA
 27 requirement applicable to the Class III medical device.” *Weber*, 940 F.3d at 1112. A
 28 plaintiff “cannot simply demonstrate a defect or a malfunction and rely on *res ipsa*

1 *loquitur* to suggest only . . . that the thing speaks for itself.” *Id.* (citation and internal
 2 quotation marks omitted). Here, however, Plaintiff has not alleged that Defendant failed
 3 to comply with federal requirements either during the PMA process or after. (*See Doc. 1.*)
 4 As such, Plaintiff has failed to allege a state law claim that fits the “narrow” exception to
 5 avoid preemption by Section 360k. *Perez*, 711 F.3d at 1120.

6 Plaintiff’s remaining allegations cannot rescue his strict liability claim. Plaintiff
 7 conclusively asserts that the Defendant is strictly liable because the STAR device is
 8 “unreasonably dangerous and unfit for its intended use and purposes because of
 9 its . . . warranty, marketing, lack of warnings and packaging.” (Doc. 1 ¶ 15.) This is the
 10 only allegation in the Complaint relating to Defendant’s warranty, marketing, lack of
 11 warnings, and packaging. (*See Doc. 1.*) As a conclusory allegation, Plaintiff has failed to
 12 state a claim for relief. *See Ashcroft*, 556 U.S. at 681 (holding that “bare
 13 assertions . . . amount[ing] to nothing more than a formulaic recitation of the
 14 elements . . . are conclusory and not entitled to be assumed true”) (internal citations and
 15 quotations omitted).

16 iii. **Count II: Negligence**

17 Plaintiff also asserts a count of negligence against Defendant, alleging “Defendant
 18 SBI negligently designed, manufactured, tested, inspected, stored, marketed, warned
 19 about, distributed, repaired, maintained, prepared and packaged” the STAR device, which
 20 constituted a breach of the standard of care. (Doc. 1 ¶ 22.) Plaintiff claims that the STAR
 21 device was defective “[a]t the time Defendant SBI placed the subject implant into the
 22 stream of commerce,” causing injury to Plaintiff. (*Id.* ¶¶ 18–26.) In the pending Motion,
 23 Defendant argues that these allegations are legally insufficient, and Plaintiff’s negligence
 24 claim is expressly preempted by Section 360k. (Doc. 10 at 8–10.)

25 To the extent Plaintiff alleges Defendant was negligent in designing and
 26 manufacturing the STAR device, that claim is expressly preempted for the same reasons
 27 Plaintiff’s strict liability claim is preempted. *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d
 28 1026, 1044 (D. Ariz. 2014) (explaining that a claim based on negligent design or

1 manufacture is expressly preempted). In *Martin*, the plaintiffs sued defendant
 2 manufacturers for negligence, after they were allegedly injured by defendant's bone graft
 3 device—a Class III device that received PMA from the FDA. *Id.* at 1031–32. In
 4 dismissing the plaintiffs' negligence claim, the court explained that any claim "based on a
 5 failure to provide warnings . . . or based on any negligence in the design and manufacture
 6 of the [Class III device]" was expressly preempted because it would impose requirements
 7 different from or in addition to the FDA requirements. *Id.* at 1044. The same is true in
 8 this action. A claim that Defendant SBI negligently designed or manufactured the STAR
 9 device would necessarily require finding that Defendant breached a duty different from or
 10 in addition to what is required by the FDA. This is precisely what Section 360k prohibits.

11 Additionally, "[n]egligence in researching, manufacturing, selling, labeling,
 12 testing, distributing, and analyzing [] are claims preempted by federal law because they
 13 all address the safety of the device in ways that the FDA considers as part of the PMA
 14 process." *Scovil*, 995 F. Supp. 2d at 1096. Therefore, Plaintiff's claims that Defendant
 15 negligently tested, inspected, stored, distributed, repaired, maintained, prepared, and
 16 packaged the STAR device are also expressly preempted. Insofar as Plaintiff alleges
 17 Defendant was negligent in marketing the STAR device, Plaintiff has not provided more
 18 than conclusory allegations and thus, has failed to state a claim for relief. *Ashcroft*, 556
 19 U.S. at 663. In sum, Plaintiff's negligence claim is dismissed.

20 **D. Leave to Amend**

21 Plaintiff has requested leave to amend his Complaint should this Court find it
 22 deficient. (Doc. 15 at 10.) Defendant argues that this request should be denied because
 23 leave to amend would be futile. (Doc. 16 at 9.)

24 Under Rule 15 of the Federal Rules of Civil Procedure, the Court "should freely
 25 give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). The liberality of
 26 Rule 15(a)(2) does not apply, however, when the amendment would be futile. *See Doe v.*
27 United States, 58 F.3d 494, 497 (9th Cir. 1995) (leave to amend should be freely given,
 28 "unless [the court] determines that the pleading could not possibly be cured by the

1 allegation of other facts”).

2 In this case, leave to amend would not be futile as Plaintiff could potentially allege
3 state law claims that parallel duties under the MDA or FDCA to avoid preemption. *See,*
4 *e.g., Jones v. Medtronic, Inc.*, 745 F. App’x 714, 717 (9th Cir. 2018) (finding that leave
5 to amend should have been granted because “a properly alleged claim of manufacturing
6 defect would not be preempted” nor would a claim based on misbranding); *Ramirez v.*
7 *Medtronic Inc.*, 961 F. Supp. 2d 977, 1003 (D. Ariz. 2013) (holding that claims based on
8 off-label promotion are not preempted by Section 360k). Accordingly, Plaintiff’s request
9 for leave to amend is granted.

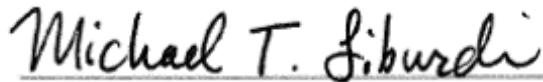
10 **IV. CONCLUSION**

11 Accordingly,

12 **IT IS ORDERED** granting Defendant’s Motion to Dismiss (Doc. 10).

13 **IT IS FURTHER ORDERED** that Plaintiff, if he chooses, shall file a First
14 Amended Complaint no later than 21 days from the date of this Order.

15 Dated this 28th day of September, 2023.

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19 Michael T. Liburdi
United States District Judge
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